

Praktik Kerja di PT Masiva Guna Periode 2-16 Mei 2023, Implementasi Aspek CDOB Keluhan, Obat Kembalian, Diduga Palsu, dan Penarikan Kembali serta Transportasi di (PBF) PT. Masiva Guna = Internship at PT Masiv Guna Period 2nd - 16th Mei 2023, Implementation of CDOB Aspects of Complaints, Returned Drugs, Counterfeit Products, and Recall and Transportation at (PBF) PT. Masiva Guna

Nur Afifah, author

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Abstrak

Pedagang Besar Farmasi yang selanjutnya disingkat PBF adalah perusahaan berbentuk badan hukum yang memiliki izin untuk pengadaan, penyimpanan, penyaluran obat dan/atau bahan obat dalam jumlah besar sesuai ketentuan peraturan perundang-undangan. Dalam menjalankan kegiatannya, PBF wajib mengikuti standar yang sudah ditetapkan dalam Cara Distribusi Obat yang Baik (CDOB) serta peraturan perundang-undangan yang berlaku. Pedoman teknis CDOB terdiri dari 12 aspek, dua diantaranya adalah aspek Keluhan, Obat Kembalian, Diduga Palsu, dan Penarikan Kembali serta aspek Transportasi. Keseluruhan aspek ini harus dipenuhi oleh setiap PBF dalam melaksanakan kegiatannya. Kesesuaian pelaksanaan aspek CDOB di PBF PT. Masiva Guna diamati melalui pelaksanaan kegiatan operasional di lapangan, dokumen-dokumen dan berdasarkan penjelasan dari Apoteker penanggung jawab serta Manager Logistik dan Distribusi di PBF PT. Masiva Guna. Hasil pengamatan yang diperoleh kemudian dibandingkan kesesuaiannya dengan aspek CDOB pada Bab 6 2.2 Keluhan, Obat, dan/atau Bahan Obat Kembalian, Diduga Palsu dan Penarikan Kembali dan Bab 7 Transportasi. Selain itu hasil pengamatan juga dibandingkan dengan poin-poin yang terdapat pada daftar periksa inspeksi diri. Berdasarkan hasil pengamatan selama pelaksanaan Praktik Kerja Profesi Apoteker (PKPA) di PT. Masiva Guna mengenai implementasi aspek CDOB Keluhan, Obat Kembalian, Diduga Palsu, dan Penarikan Kembali serta Transportasi disimpulkan bahwa telah sesuai. Hal ini dibuktikan berdasarkan hasil pengamatan, bertanya langsung dan pengecekan menggunakan daftar periksa inspeksi diri yang dikeluarkan oleh BPOM. Selain itu kesesuaiannya juga dapat dibuktikan dengan adanya sistem dan dokumen Prosedur Operasional Baku (POB) yang telah dibuat dan diterapkan oleh PT. Masiva Guna. Pharmaceutical Wholesaler, hereinafter abbreviated as PBF, is a company in the form of a legal entity that has a license to procure, store, distribute drugs and/or medicinal materials in large quantities in accordance with statutory provisions. In carrying out its activities, PBF must follow the standards set out in the Cara Distribusi Obat yang Baik (CDOB) and the prevailing laws and regulations. The CDOB technical guidelines consist of 12 aspects, two of which are aspects of Complaints, Drug Returns, Suspected Counterfeits, and Recalls and aspects of Transportation. All of these aspects must be fulfilled by every PBF in carrying out its activities. The suitability of the implementation of CDOB aspects at PBF PT Masiva Guna was observed through the implementation of operational activities in the field, documents and based on explanations from the Pharmacist in charge and the Logistics and Distribution Manager at PBF PT Masiva Guna. The results of the observations obtained were then compared with the CDOB aspects in Chapter 6 2.2 Complaints, Drug, and/or Drug Ingredients Returned, Suspected Counterfeit and Recalled and Chapter 7 Transportation. In addition, the observation results were also compared with the points contained in the self-inspection

checklist. Based on the results of observations during the implementation of the Pharmacist Professional Work Practice (PKPA) at PT Masiva Guna regarding the implementation of the CDOB aspects of Complaints, Returned Drugs, Suspected Counterfeits, and Recalls and Transportation, it is concluded that it is appropriate. This is evidenced by the results of observations, direct questions and checking using the self-inspection checklist issued by BPOM. In addition, its suitability can also be proven by the existence of a system and Standard Operating Procedure (POB) documents that have been created and implemented by PT Masiva Guna.